

PTO/SB/08A (10-01)

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			Application Number	10/816,698	
			Filing Date	April 2, 2004	
			First Named Inventor	Mien-Chie Hung	
			Art Unit	1645	
			Examiner Name	Not Yet Assigned	
Sheet	1	of	3	Attorney Docket Number	AH-UTSC:791US

U.S. PATENT DOCUMENTS					
Examiner Initials*	Cite No. <sup>1</sup>	Document Number Number-Kind Code <sup>2</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
	AA*	US-6,638,762	10-28-2003	Chang et al.	

FOREIGN PATENT DOCUMENTS						
Examiner Initials*	Cite No. <sup>1</sup>	Foreign Patent Document Country Code <sup>3</sup> -Number <sup>4</sup> -Kind Code <sup>5</sup> (if known)	Publication Date MM-DD-YYYY	Name of Patentee or Applicant of Cited Document	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>6</sup>
	BA	WO-98/33903	08-06-1998	Molloy		
	BB	AU-5742198	08-25-1998	Molloy		
	BC	WO-00/26343	05-11-2000	Eckert et al.		
	BD	EP-1009820	06-21-2000	Molloy		
	BE	JP-2001218587	08-14-2001	Chao		

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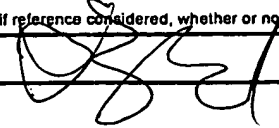
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	CA	Anderson et al., "Breast cancer-specific expression of the <i>Candida albicans</i> cytosine deaminase gene using a transcriptional targeting approach," <i>Cancer Gene Therapy</i> , 7(6): 845-852, 2000.		
	CB	Bauman et al., "Differential Immunohistochemical Staining for DNA Topoisomerase II $\alpha$ and $\beta$ in Human Tissues and for DNA Topoisomerase II $\beta$ in Non-Hodgkin's Lymphomas," <i>Mod. Pathol.</i> , 10(3): 168-175, 1997.		
	CC	Casey et al., "Deletional analysis of the promoter region of the human transferrin receptor gene," <i>Nucleic Acids Research</i> , 16(2): 629-646, 1988.		
	CD	Donello et al., "Woodchuck Hepatitis Virus Contains a Tripartite Posttranscriptional Regulatory Element," <i>J. Virology</i> , 72(6): 5085-5092, 1998.		
	CE	Fuernkranz et al., "Differential tissue localization of oviduct and erythroid transferrin receptors," <i>Proc. Natl. Acad. Sci. USA</i> , 88: 7505-7508, 1991.		
	CF	Guillou et al., "Sertoli Cell-specific Expression of the Human Transferrin Gene: Comparison with the Liver-specific Expression," <i>J. Biol. Chem.</i> , 266(15): 9876-9884, 1991.		
	CG	Hirsch et al., "Mitogenic activation of the transferrin receptor gene promoter i modulated by inhibitors of tyrosine kinases and tyrosine phosphatases," <i>Recept Signal Transduct.</i> , 6(3-4): 121-9, 1996.		
	CH	Hochhauser et al., "Cloning and characterization of the 5' flanking region of the human topoisomerase II alpha gene," <i>J. Biol. Chem.</i> , 267(26): 18961-5, 1992.		
	CI	Idzerda et al., "Expression from the Transferrin Gene Promoter in Transgenic Mice," <i>Mol. Cell. Biol.</i> , 9(11): 5154-5162, 1989.		
	CJ	Isomura et al., "The Human Cytomegalovirus Major Immediate-Early Enhancer Determines the Efficiency of Immediate-Early Gene Transcription and Viral Replication in Permissive Cells at Low Multiplicity of Infection," <i>Journal of Virology</i> , 77(6): 3602-3614, 2003.		
	CK	Iyer et al., "Two-step transcriptional amplification as a method for imaging reporter gene		
Examiner Signature			Date Considered	3/17/06

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		expression using weak promoters," <i>PNAS</i> , 98(25): 14595-14600, 2001.	
CL		Katabi et al., "Hexokinase Type II: A Novel Tumor-Specific Promoter for Gene-Targeted Therapy Differentially Expressed and Regulated in Human Cancer Cells," <i>Human Gene Therapy</i> , 10: 155-164, 1999.	
CM		Kawabata, "Regulation of expression of murine transferrin receptor 2," <i>Blood</i> , 98(6): 1949-1954, 2001.	
CN		Kugler et al., "Tissue-specificity of liver gene expression: a common liver-specific promoter element," <i>Nucleic Acids Research</i> , 16(8): 3165-3174, 1988.	
CO		Lu et al., "Enhanced Gene Expression in Breast Cancer Cells <i>in Vitro</i> and Tumors <i>in Vivo</i> ," <i>Molecular Therapy</i> , 6(6): 783-792, 2002.	
CP		Maeda et al., "A minimum c-erbB-2 promoter-mediated expression of herpes simplex virus thymidine kinase gene confers selective cytotoxicity of human breast cancer cells to ganciclovir," <i>Cancer Gene Therapy</i> , 8(11): 890-896, 2001.	
CQ		Mendelzon et al., "The binding site for the liver-specific transcription factor Tf-LF1 and the TATA box of the human transferrin gene promoter are the only elements necessary to direct liver-specific transcription <i>in vitro</i> ," <i>Nucleic Acids Research</i> , 18(19): 5717-5721, 1990.	
CR		Mo et al., "Overexpression of human DNA topoisomerase II alpha by fusion to enhanced green fluorescent protein," <i>Biotechnol.</i> , 25(6): 1052-7, 1998.	
CS		Qiao et al., "Tumor-specific transcriptional targeting of suicide gene therapy," <i>Gene Therapy</i> , 9: 168-175, 2002.	
CT		Radetzki et al., "The apoptosis promoting Bcl-2 homologues Bak and Nbk/Bik overcome drug resistance in Mdr-1-negative and Mdr-1-overexpressing breast cancer cell lines," <i>Oncogene</i> , 21(2): 227-38, 2002.	
CU		Sandford et al., "Rat Cytomegalovirus Major Immediate-Early Enhancer Switching Results in Altered Growth Characteristics," <i>Journal of Virology</i> , 75(11): 5076-5083, 2001.	
CV		Sato et al., "Optimization of adenoviral vectors to direct highly amplified prostate-specific expression for imaging and gene therapy," <i>Mol. Ther.</i> , 8(5): 726-37, 2003.	
CW		Shindelman et al., "Demonstration of the Transferrin Receptor in human breast cancer tissue. Potential marker for identifying dividing cells," <i>Int. J. Cancer</i> , 27:329-334, 1981.	
CX		Shterman et al., "Comparison of Transferrin Receptors, Iron Content and Isoferritin profile in normal and malignant human breast cell lines," <i>Pathobiol.</i> , 59: 19-25, 1991.	
CY		Theisen et al., "A C/EBP-Binding Site in the Transferring Promoter Is Essential for Expression in the Liver but Not the Brain of Transgenic Mice," <i>Mol. Cell. Biol.</i> , 13(12): 7666-7676, 1993.	
CZ		Tong et al., "The Pro-apoptotic Protein, Bik, Exhibits Potent Antitumor Activity That Is Dependent on Its BH3 Domain," <i>Molecular Cancer Therapeutics</i> , 1: 95-102, 2001.	
CA1		Verma et al., "Structural analysis of the human pro-apoptotic gene <i>Bik</i> : Chromosomal localization, genomic organization and localization of promoter sequences," <i>Gene</i> , 254(1-2): 157-162, 2000.	
CB1		Xie et al., "Adenovirus-mediated tissue-targeted expression of a caspase-9-based artificial death switch for the treatment of prostate cancer," <i>Cancer Res.</i> , 61(18): 6795-804, 2001.	
CC1		Zakin, "Regulation of transferrin gene expression," <i>The FASEB Journal</i> , 6: 3253-3258, 1992.	
CD1		Zhang et al., "A Gene-Specific Promoter in Transgenic Mice Directs Testis-Specific Demethylation Prior to Transcriptional Activation <i>In Vivo</i> ," <i>Biology of Reproduction</i> , 59: 284-292, 1998.	
CE1		Zhang et al., "A small composite probasin promoter confers high levels of prostate-specific gene expression through regulation by androgens and glucocorticoids <i>in vitro</i> and <i>in vivo</i> ," <i>Endocrinology</i> , 141(12): 4698-710, 2000.	
CF1		Zhang et al., "Molecular engineering of a two-step transcription amplification (TSTA) system for transgene delivery in prostate cancer," <i>Mol. Ther.</i> , 5(3): 223-32, 2002.	

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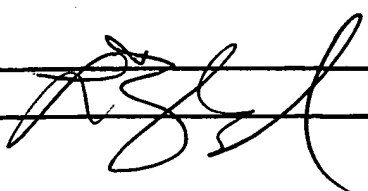
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	BA	WO-99/16787		04-08-1999			

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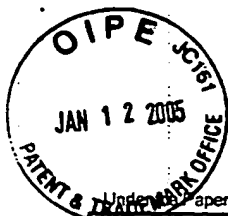
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	CA	Elangovan, B. et al.; "Functional dissection of the pro-apoptotic protein bik: Heterodimerization with anti-apoptosis proteins is insufficient for induction of cell death". J. Biol. Chem., (1997) Vol. 272, No. 39, pp. 24494-24498.	
	CB	Boyd, J., et al., "Bik, a Novel Death-Inducing Protein Shares a Distinct Sequence Motif with Bel-2 Family Proteins and Interacts with Viral and Cellular Survival-Promoting Proteins", Oncogene (1995) Vol. 11, No. 9, pp. 1921-1928.	
	CC	Li, Y. et al.; "Enhancement of Bik antitumor effect by Bik Mutants." Cancer Research, (2003), Vol. 63, No. 22, pp. 7630-7633.	

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		60/559,111	04-02-2004	Hung, Mien-Chie, et al.	

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	CA	Bartke, T., et al.; p53 upregulates cFLIP, inhibits transcription of NF-kB-regulated genes and induces caspase-8-independent cell death in DLD-1 cells, Oncogene (2001) Vol. 20, pp. 571-580.	
	CB	Zou, Yiyu, et al.; Systemic tumor suppression by the proapoptotic gene bik1, Cancer Research (January 2002), Vol. 62, pp. 8-12.	
	CC	Daniel, Peter T. et al.; Expression of the death gene bik/Nbk promotes sensitivity to drug-induced apoptosis in corticosteroid-resistant t-cell lymphoma and prevents tumor growth in severe combined immunodeficient mice, Neoplasia (August 1999) Vol. 94, No. 3, pp. 1100-1107.	
	CD	Han, Jeonghoon, et al.; induction of apoptosis by human Nbk/Bik, a BH3-containing protein that interacts with E1B 19K, Molecular and Cellular Biology (October 1996), pp. 5857-5864.	
	CE	Panaretakis, Theocharis, et al.; Activation of bak, bax, and BH3-only proteins in the apoptotic response to doxorubicin, Journal of Bio. Chem. (November 2002), Vol. 277, No. 46, pp. 44317-44326.	
	CF	Friedman, Debbie, et al.; Ecteinascidin-743 inhibits activated but not constitutive transcription, Cancer Research, (June 2002) Vol. 62, pp. 3377-3381.	
	CG	Verma, Sulekha, et al.; Phosphorylation of the pro-apoptotic protein BIK, Journal of Bio. Chem., (February 2001) Vol. 276, No.7, pp. 4671-4676.	

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